Legislation of Interest – 113th Congress

The following bills were selected for inclusion due to ongoing interest among the cancer community.

Early Act Reauthorization of 2014 (H.R. 5185/S. 2655; 113th Congress)

- The bill aims to reauthorize the Young Women's Breast Health Education and Awareness Requires Learning Young (EARLY) Act of 2009 for a period of 5 years. The EARLY Act was originally signed into law as section 10413 of the Patient Protection and Affordable Care Act (Public Law 111-148) on 3/23/10.
- Consistent with the original law, the reauthorization proposes to increase awareness of breast cancer risks in young women (15 39 years old) and to provide support for those diagnosed with breast cancer.
- The reauthorization would direct CDC to continue implementation of the EARLY Act provisions signed into law in 2010 and does not include new provisions. The bill would direct the CDC to continue to conduct a national evidence-based education campaign to increase public awareness regarding breast cancer in young women, especially regarding risks faced by ethnic and cultural groups. Additionally, the bill would direct the CDC, in consultation with HRSA, to continue an education campaign to increase awareness among physicians and other health care professionals of risk factors, risk reduction strategies, early diagnosis and treatment of breast cancer in young women.
- The bill would also direct the CDC to continue to conduct prevention research on breast cancer in younger women; continue to support research aimed at measuring their awareness of the disease; and continue the activities of its Advisory Committee on Breast Cancer in Young Women.
- The bill would authorize \$9 M for each fiscal year from 2015 through 2019.
- Reps. Debbie Wasserman Schultz (D-FL) and Renee Ellmers (R-NC) introduced H.R. 5185 on 7/24/2014, and Sens. Amy Klobuchar (D-MN) and David Vitter (R-LA) introduced S. 2655 on 7/24/14. H.R. 5185 was referred to the Committee on Energy and Commerce, and S.2655 was referred to the Committee on Health, Education, Labor, and Pensions. The House passed H.R. 5185 on 12/9/14 by voice vote and the Senate passed it by unanimous consent on 12/15/14. **The President signed it into law (P.L. 113-265) on 12/18/2014.**
- Link to Congress.gov

Sunscreen Innovation Act (H.R. 4250/S. 2141, 113th Congress)

- The bills aim to accelerate FDA review and approval of sunscreens with new active ingredients. FDA's Center for Drug Evaluation and Research would be required to complete its review of eligible applications within 300 days of the request being filed. If the center did not act within that time, the request would be transferred to the FDA Commissioner for review within 60 days.
- Provisions in the bills are specific to FDA, and NCI would not have any responsibility for implementation.
- H.R. 4250 was originally introduced by Rep. Ed Whitfield (R-KY) on 3/13/14, and Sens. Jack Reed (D-RI) and Johnny Isakson (R-GA) introduced a companion bill, S. 2141 on the same date. The Senate passed S. 2141 on 9/17/14, agreeing to the measure

by Unanimous Consent. The House passed S. 2141 by unanimous consent on 11/13/14. **The President signed it into law (P.L. 113-195) on 11/26/2014.**

• <u>Link to Congress.gov</u>

Continuing Appropriations Resolution, 2015 (H.J. Res. 124; 113th Congress; P.L. 113-364)

- The continuing resolution (CR) would provide funding for federal government operations at FY 2014 levels through 12/11/2014 at an annualized rate of \$1.012 trillion.
- Among other measures, it would provide \$88 million for government efforts to fight the Ebola virus.
- It would also allow the FDA to collect fees for the inspection of compounded drugs.
- Rep. H. Rogers (R-KY) introduced the CR on 9/9/2014. The CR was referred to the House Appropriations and the House Budget Committees; passed by the House on 9/17 and passed by the Senate on 9/18. **The President signed it into law (P.L. 113-364) on 9/19/2014.**
- Link to Congress.gov

Accelerating Biomedical Research Act (S.2658/H.R. 5580; 113th Congress)

- The bill aims to restore funding to NIH and provide a predictable funding plan. It would establish a budget cap adjustment that would allow for additional funds to be appropriated to NIH if Appropriators maintain at least \$29.9 billion in NIH funding.
- The bill would maintain the current funding of \$29.9 billion for NIH for FY2015, and aims to increase appropriations to \$46.5 billion by the end of FY 2021. These provisions would restore NIH funding to the 2003-post doubling level, recognizing that since 2003, budget caps and other funding constraints have resulted in significant erosion of NIH purchasing power.
- The NIH would receive an initial increase of 10% in each of the first two fiscal years, FY 2015 and FY 2016, to mitigate the effects of sequestration; and thereafter an increase of 5% in each of the remaining years.
- Sen. Tom Harkin (D-IA) introduced S. 2658 on 7/24/14. Rep. Rosa DeLauro (D-CT) introduced H.R. 5580 on 9/18/14. The bills were refereed to the Senate and House Budget Committees, respectively.
- Link to Congress.gov

Next Generation Research Act (S.1552/H.R. 5451; 113th Congress)

- The main goal of this bill is to increase opportunities for the development of our next generation of researchers through the establishment of the Next Generation of Research Initiative within the National Institutes of Health (NIH). The proposed initiative would promote efforts aimed at improving opportunities for new researchers including efforts to strengthen mentorship programs pairing new and veteran researchers, to enhance workforce diversity efforts, and to help improve new researchers' success in obtaining renewal funding.
- The bill would require the National Academy of Sciences (NAS) to conduct a comprehensive study of legislative, administrative, educational, and cultural barriers to providing for a successful next generation of biomedical researchers.

- In addition, a report to Congress would be required within five years of the date of enactment concerning the results of the NAS study including an evaluation of the impact of sequestration on the next generation of researchers and recommendations for the implementation of policies to incentivize, improve entry to, and sustain careers in research.
- S. 1552 was originally introduced by Sen. Tammy Baldwin (D-WI) on 9/26/13 and was referred to the Senate HELP Committee. Rep. Mark Pocan (D-WI) introduced a companion bill, H.R. 5451, on 9/11/2014. The bill was referred to the House Committee on Energy and Commerce.
- Link to Congress.gov

Breast Density and Mammography Reporting Act (S. 2622/H.R. 5145, 113th Congress)

- The bill would amend the Mammography Quality Standards Act (MSQA) of 1992 to require mammography results to include information about a patient's breast density, and for that information to be reported to patients in their mammography results summary.
- The bill directs the Health and Human Services (HHS) Secretary to establish reporting requirements based on current scientific knowledge, and also requires that the summary communicate the effect of dense breast tissue in masking breast cancer on mammography. For women with results indicating they have dense breast tissue, the summary must also include language encouraging them to consult with their physician regarding whether additional screening would be beneficial.
- The bill also directs the HHS to "expand and intensify" HHS programs related to (1) applied research on breast density; (2) research on the cost-effectiveness, effectiveness, and feasibility of reimbursement models for supplemental imaging related to breast density; (3) research supporting clinical guidelines and best practices for mammography screening for women with dense breasts.
- Rep. Rosa DeLauro (D-NY) and Rep. Steve Israel (D-NY) introduced H.R. 5154 in the House on 7/17/2014, and the bill was referred to the Committee on Energy and Commerce. Sens. Dianne Feinstein (D-CA) and Kelly Ayotte (R-NH) introduced S. 2622, companion bill to H.R. 5154, on 7/17/2014. The bill was referred to the Committee on Health, Education, Labor and Pensions.
- Link to Congress.gov

Removing Barriers to Colorectal Cancer Screening Act of 2014 (S.2348)

- The bill aims to amend title XVIII of the Social Security Act to waive coinsurance under Medicare for colorectal cancer screening tests, regardless of whether therapeutic intervention is required during the screening. This would provide for full coverage of colorectal cancer screening tests under Medicare part B.
- S.2348 was introduced by Sen. Sherrod Brown (D-OH) on 5/15/14 and was referred to the Committee on Finance.
- Link to Congress.gov

Gabriella Miller Kids First Research Act (H.R.2019/Signed into law as P.L. 113-94)

- This law amends the Internal Revenue Code to eliminate taxpayer financing of political party conventions and to reprogram savings to provide for a 10-year pediatric research initiative administered through the National Institutes of Health Common Fund.
 - o The bill calls for funds for political conventions currently in accounts maintained by national committees of political parties to be transferred to a fund in the Treasury to be known as the "10-Year Pediatric Research Initiative Fund" in the amount of \$12.6 million per year for fiscal years 2014-2023.
 - The funds are to be made available to NIH Common Fund "in such amounts as are provided in advance in appropriation Acts."
 - Effect of the law is limited to identifying a specific source of funds and authorizing an appropriation to the NIH Common Fund. By itself, the law does not actually provide any funds to NIH.
 - O As pointed out by Reps. Nita Lowey (D-NY) and Rosa DeLauro (D-CT) (Ranking Members of the House Appropriations Committee and Labor-HHS Appropriations Subcommittee, respectively), in order for NIH to receive such funds, Congressional Appropriators must include a specific appropriation of funds in the Labor-HHS Appropriations Act, which has yet to be finalized for FY 2015. If this does not happen, the funds remain in the Treasury "10-Year Pediatric Research Initiative Fund" indefinitely. Reps. Lowey and DeLauro also noted that the appropriations needed to make these funds available would be fully subject to the spending caps in place under the Budget Control Act, and to the budget resolution spending allocations to the Appropriations Committee and Labor-HHS Subcommittee. This means that an increase in appropriations to NIH by the "10-Year Pediatric Research Initiative Fund" would need to be offset by a reduction elsewhere in the Labor-HHS-Education bill.
- H.R. 2019 was introduced by Rep. Gregg Harper on 5/16/13, as the Kids First Research Act, and was renamed in honor of Gabriella Miller, a 10-year-old girl from Virginia who passed away in October 2013 due to a pediatric brain tumor, Diffuse Intrinsic Pontine Glioma.
- H.R. 2019 was referred to the House Energy and Commerce Committee, Subcommittee on Health, as well as the House Committees on Administration, and Ways and Means. The bill did not proceed through mark up and was not passed out of committee. On 12/11/13, the House passed the bill under suspension of the rules, in a vote of 295-103. On 3/11/13, the Senate passed the bill by unanimous consent. **The President signed** the bill into law on 4/4/14.
- Link to Congress.gov

American Cures Act/ America HEALS Act (S. 2115/H.R. 4384)

• The bill proposes to establish a Biomedical Research Fund, to be administered by the Secretary of Treasury, and authorizes funding to be appropriated to support an expanded and sustained national investment in biomedical research by increasing funding for eligible programs within the NIH, the Centers for Disease Control and Prevention, the Department of Defense and the Department of Veterans Affairs.

- The bill proposes \$150 billion in mandatory funding over 10 years, starting with \$1.8 billion in the first year. Each year, the bill would increase funding for each agency and program at a rate of GDP-indexed inflation plus 5 percent.
- S. 2115 was introduced by Sen. Richard Durbin (D-IL) on 3/12/14 and was referred to the Health, Education, Labor, and Pensions (HELP) Committee.
- Rep. Anna Eshoo (D-CA) introduced the America HEALS (Helping Encourage Advancements in Lifesaving Science) Act, H.R. 4384 on 4/3/14. Other than their titles, S. 2115 and H.R. 4384 are identical. H.R. 4348 was referred to the House Energy and Commerce Committee, Subcommittee on Health.
- Link to Congress.gov

Cancer Treatment Parity Act of 2013/Cancer Drug Coverage Parity Act of 2013 (S.1879/H.R. 1801)

- The bill aims to require health insurers to provide for coverage of oral anticancer drugs on terms no less favorable than the coverage provided for anticancer medications administered by a health care provider.
 - For the Patient-administered medication, the provider can charge annual deductibles, coinsurance, copayments, as long as they do not exceed payments for anticancer medications administered by a health care provider under the plan or coverage for the same purpose.
 - The provider cannot increase in out-of-pocket costs of anticancer medications; reclassify anticancer medications benefits; or apply more restrictive limitations on prescribed oral, intravenous or injected anticancer medications.
- S. 1879 was introduced on 12/19/13 by Sen. Al Franken (D-MN) and was referred to the Committee on Health, Education, Labor, and Pensions. H.R. 1801 was introduced on 4/26/13 by Rep. Brian Higgins (D-NY), and was referred to the House Committees on Energy and Commerce (Subcommittee on Health), Ways and Means, and Education and the Workforce (Subcommittee on Health, Education, Labor, and Pensions).
- The bills include nearly the same proposals, however the Senate bill calls for provisions to apply to health plans for plan years beginning on or after January 1, 2015, whereas the House bill would apply to health plans beginning on or after January 1, 2014.
- Link to Congress.gov

Pediatric, Adolescent, and Young Adult Cancer Survivorship Research and Quality of Life Act (S. 1247; 113th Congress)

- The bill authorizes \$15 million each year for five years for the HHS Secretary to award grants for pilot programs to develop or evaluate model systems for monitoring and caring for childhood cancer survivors.
- The bill authorizes an additional \$5 million each year for five years for the HHS Secretary to establish a Workforce Development Collaborative on Medical and Psychosocial Care for Pediatric Cancer Survivors. The collaborative would include educators, consumer and family advocates, and providers of psychosocial and biomedical health services.
- Introduced by Sen. Jack Reed (D-RI) on 6/27/13 and referred to the Committee on Health, Education, Labor, and Pensions.
- Link to Congress.gov